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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/175,713 10/20/98 HERRMANN

S GI-5302-CON

EXAMINER

HM22/0730

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ART UNIT

PAPER NUMBER

1646

DATE MAILED:

07/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Advisory Action**

Application No.

09/175,713

Applicant(s)

HERRMANN ET AL.

Examiner

Janet L Andres

Art Unit

1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 July 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1-14, 17 and 18.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

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TECHNOLOGY CENTER 1600

Continuation of 5. does NOT place the application in condition for allowance because: 1. Applicant argues that adequate written description is provided because the claims are drawn to a specifically enumerated set of amino-terminal modified chemokines. Applicant argues that the claims are drawn to compositions, rather than their functional characteristics and it is impermissible to read a functional limitation into the claims. Applicant's arguments are not found persuasive because Applicant states on page one of the specification that the invention relates to amino-terminal modified chemokines and the use of such chemokines to inhibit the interaction between chemokine receptors and naturally occurring ligands (lines 11-13). Thus the functional characteristics of the claimed molecules are essential to what Applicant has described on the first page and throughout the specification as the invention. Further, the claims are drawn to molecules "comprising at least one" of a number of possible modifications and thus are not "specifically enumerated"; the open language encompasses a potentially infinite number of species. Since both the chemokines and the modifications claimed encompass structurally unrelated molecules, the species are, as stated in the previous Office Action, widely diverse. Thus a description of the common attributes or features of inhibitory chemokines is not set forth, and one of skill would not recognize that Applicant was in possession of the invention described in the specification.

2. Applicant argues that the specification is enabling for the invention because all that is required is knowledge of the nucleotide sequences of the listed chemokines along with a method of producing the amino-terminal modified form of one of the chemokines. Applicant argues that as long as the specification discloses at least one method for making and using the invention that bears a reasonable correlation to the entire scope of the claim the enablement requirement is satisfied. Applicant's arguments are not found persuasive because they are not commensurate with the scope of the claims. What is set forth in the specification as Applicant's invention are amino-terminally modified molecules that are inhibitors of receptor/ligand binding. Enablement of the claimed invention requires that Applicant teach both how to make and use it. As stated above and in the previous Office Actions, the claims encompass many different and structurally varied molecules, including sequences with internal variations. Since the prior art teaches that the effects of the claimed modifications are unpredictable, one of skill in the art would not be able to predict which of the many possible modified chemokines would function in accordance with what Applicant has described as the invention. Thus one of skill in the art would be able to make the modified proteins, but would not be able to predict which could actually be used. It is this lack of predictability as to which of the many possible embodiments of the claims would function as Applicant has described that renders the required experimentation undue.

3. Applicant argues that the claims are not indefinite because "fragments" and "stringent hybridizing conditions" are defined in the specification. Applicant argues that the statement on p. 20 is a definition of "fragment". This is not found persuasive because the statement requires that the fragment "retain the desired activity" or "modify it to create a desired activity". There is no limitation as to what such desired activities might encompass and Applicant has in fact argued that no such limitations are required by the claims. Thus one of skill in the art would not be able to determine what such fragments might be. Applicant further argues that stringent conditions are defined on p. 22. This is not found persuasive because, as stated in the previous office action, the conditions provided are merely examples. See p. 22, line 14: "highly stringent conditions include, for example..." and line 16, "Preferably, such hybridizing polynucleotides..."